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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,005	07/03/2003	Juergen Andrew Kortenbach	06530.0170-05	3367

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EXAMINER	
YABUT, DIANE D	
ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
10/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/612,005	KORTENBACH, JUERGEN ANDREW	
	Examiner	Art Unit	
	Diane Yabut	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *110-137* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *110-137* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06 July 2007 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims **110-124 and 128-137** are rejected under 35 U.S.C. 102(e) as being anticipated by **Bolanos** (U.S. Patent No. **5,897,562**).

Claims 110-116, 129-137: Bolanos discloses an elongated tube **18** having a proximal end for extending outside of the body and a distal end for positioning proximate the multiple tissue layers, a distal member **22** configured to fold the multiple tissue layers together or for folding a fundus of a stomach toward an esophageal wall, the distal member comprising a first member **38** having a proximal end coupled to the distal end of the tube and a second member **26** pivotably coupled to the distal end of the first member, being pivotable between an open position for receiving the multiple tissue layers and a closed position for folding the multiple tissue layers therebetween, at least one of the first and second members being configured to install at least one fastener **30** configured to fasten the multiple tissue layers when the first member and the second member hold first and second parts of the fastener, respectively, and a grasper (ridges on either **38** or **26**, or between the first and second members) coupled to one of the distal member and the tube for grasping a portion of at least one of the multiple tissue layers (Figures 1 and 12-15).

Bolanos discloses an elongated tube **90** having a proximal end and a distal end, having a distal member **92,102** configured to fold the multiple tissue layers together, the distal member comprising a first member **92** having a proximal end coupled to the distal end of the tube and a distal end, a second member **104** pivotably coupled to the distal end of the first member (Figures 19-20), at least one of the first and second members being configured to install at least one fastener configured to fasten multiple tissue

layers and having a first part and a second part, the first member being configured to hold the first part and the second member being configured to hold the second part in opposed relation with the first part (Figures 27-28), and a grasper including a first grasper (the other ref. **104**) rotatably coupled to the first member for grasping a portion of at least one of the multiple tissue layers (Figures 20-21) and the first grasping member including a first grasping surface and the first member including a second grasping surface configured to engage with the first grasping surface so as to grasp the portion of at least one of the multiple tissue layers therebetween, the grasper located between the first or stationary member and the rotatable member – specifically the proximal end of the stationary member **92** and an extended second member **104** can be considered as being on either side of a closed grasper **104** (Figure 24).

Bolanos discloses the second member or rotatable member **104** having a connected end **110** connected to the distal end of the first member or stationary member **92** and a free end, and the second member being configured to pivot between a first position in which the free end is located distally of the connected end and a second position in which the connected end is located distally of the free end (Figures 21-22).

Claims 117-120: Bolanos discloses a control member or actuator **112** located or coupled proximate the proximal end of the tube configured to control operation of at least one of the distal member and the grasper, the control member located proximate the proximal end of the tube and comprising at least one control cable extending form the control member to at least one of the distal member and the grasper through the

tube, and the tube including a port for an endoscope **102** and wherein the grasper is capable of grasping a gastroesophageal junction (Figures 19 to 21, col. 8, line 55 to col. 9 line 4).

Claims 121-124 and 128: Bolanos discloses a method of performing invagination, which comprises providing the surgical instrument of claim 110, inserting the surgical instrument transorally into a stomach, grasping a portion of the fundus or the esophageal wall with the grasper, and folding the fundus toward the esophageal wall with the distal member, while grasping the portion of the fundus or the esophageal wall, and the grasper being integrally formed with the distal member, the distal member including a stationary member, the rotatable member being pivotably coupled to the stationary member, and the step of folding the fundus including rotating the rotatable member with respect to the stationary member so as to fold the fundus toward the esophageal wall and applying at least one fastener to secure the fundus to the esophageal wall (Figures 19-28; col. 3, lines 10-21, col. 9, lines 34-65).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims **125-127** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bolanos** (U.S. Patent No. **5,897,562**) in view of Harrison (U.S. Patent No. 5,403,326).

Claims 125-127: Bolanos discloses the claimed device, including actuating an actuator **112** located or coupled proximate the proximate end of the tube configured to control operation of at least one of the distal member and the grasper **104** (Figures 19 to 21, col. 8, line 55 to col. 9 line 4), except for being used for engagement between male and female members of a fastener.

Harrison teaches a grasper **72** being used for engagement between male and female members of a fastener (col. 8, lines 1-10). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a control member being used for engagement between male and female members of a fastener, as taught by Harrison, to Bolanos since it was known in the art that male and female, or two-part fastener members, are common in the art to provide secure engagement with tissue to prevent undesirable movement.

Bolanos discloses the claimed device except for a fastener having a male member and a female member, and the rotatable member being configured to hold one of the male member and female members, the distal member further comprising a stationary member coupled to the rotatable member and configured to hold another of the male and female members in opposed relation with the one of the male and female members, and rotating the rotatable member with respect to the stationary member so as to cause engagement between the male and female members.

Harrison teaches a fastener having a male member **92**,**94** and a female member **96**, and the rotatable member being configured to hold one of the male member and female members, the distal member further comprising a stationary member coupled to

the rotatable member and configured to hold another of the male and female members in opposed relation with the one of the male and female members, and rotating the rotatable member with respect to the stationary member so as to cause engagement between the male and female members (Figure 8C-8D).

It is noted that one of the male member and female members is considered stationary once it grasps the tissue and another of the male and female members can rotate towards the stationary member (angular displacement). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the male and female members, as taught by Harrison, to Bolanos since it was known in the art that male and female, or two-part fastener members, are common in the art to provide secure engagement with tissue to prevent undesirable movement, and that rotation in the process of applying fastener members facilitates the device maneuvering around tissue and layers of tissue.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER